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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/565,320

01/18/2006

Bernd Meyer

23506

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535 7590 12/13/2007

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EXAMINER

DANEGA, RENEE A

ART UNIT

PAPER NUMBER

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/565,320	<b>Applicant(s)</b> MEYER ET AL.	
	<b>Examiner</b> Renee Danega	<b>Art Unit</b> 4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 January 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/18/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Objections***

1. Claims 1, 3, and 8-11 are objected to because of the following informalities:
  - Claim 1 is written to a device while the specification states it to be a method. Examiner took it to be a method. Claim 1 is also not a grammatical sentence.
  - Claim 3 is a device dependent on method claim 1. Examiner took it to be a method.
  - Claims 8-10 are device claims dependent on claim 3. Examiner took them to be dependent on device claim 6.
  - Claim 11 makes reference to "the light sources" which are not present in claim 10.

Appropriate correction is required.

### ***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.

- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

### ***Drawings***

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 6 and 11. 6 is referred to on page 13, but what 6 represents is not stated. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be

notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-6, and 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claims 1-5 and 8-10 are indefinite since it is not clear whether these claims should be method claims or article claims. Claims 2, 4, and 5 are indicated to be method claims but they lack any “method steps” as required in method claims. Claims 1 and 3 are written as article claims (a device) but it appears these claims were meant to be written as method claims. If this is the case, these claims should be amended to include the necessary method steps.
- In claim 1, line 2, “especially neuropathies” makes the claim indefinite.
- In claim 1, lines 2-3, “at least one device” is indefinite because it is not clear whether the applicant is referring to the device in line 1 or to an additional “device”
- In claim 1, line 4, “especially a person” makes the claim indefinite.
- In claim 6, line 2, “especially neuropathies” makes the claim indefinite.

- In claim 8, line 3, “especially such that...” makes the claim indefinite.
- In claim 7, lines 3-4, “a sensor” is indefinite since it is unclear whether the sensor is the same as the sensor defined in claim 6 or if it is an additional sensor. It is also not clear whether the sensor is being positively claimed.

### ***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 6, 7, 9, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Demand (US 4759712).

- Regarding claim 6, Demand teaches a device for determining thermal sensitivity of nerve sensitive tissue in which a means for producing an air stream, or pressurized fluid (i.e. air) source is connected to source line (92) (Figure 1, column 5, lines 8-10). It comprises a probe assembly (20) capable of directing air (figure 1) and a sensor (50) within tube (20) for measuring temperature of exiting air stream. The examiner notes that this would be useful in determining perceived temperature and that the device would be capable of being used to determine sensory disorders.
- Regarding claim 7, sensor (50) is capable of measuring air temperature.
- Regarding claim 9, temperature display (82) would be capable of indicating a perceived temperature and feedback (52) of temperature sensor (50) would allow for determining of perceived temperature.

- Regarding claim 10, the device has a portable probe, which would be capable of being moved varying distances from the target.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-3 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gafni et al. (US 5191896) in view of Demand (US 4759712). Gafni teaches a method of measuring sensory threshold which is used in the determination of sensory disorders in which a device is provided to measure thermal sensitivity using a plurality of methods such as method of limits, which is known to be a method of increasing a stimulus is detected or lowering it until no longer detected, thus correlated to a perception of temperature (column 1, lines 35-50). Gafni teaches using a skin temperature sensor (22) to communicate body surface temperature with the computer (figure 1, column 2, lines 50-54). Gafni doesn't teach directing an air stream onto the measurement area. However, Demand teaches a nerve sensitivity measuring apparatus, which uses pressurized fluid defined to be air (column 6, lines 29-32). It would have been obvious in view of Demand to use forced air in Gafni's method in order to remove possible influences on perception of using solid object in contact with the test area.

- Regarding claims 2-3, Gafni teaches using two time periods during which the stimulus is present and is not present (column 4, lines 13-15). Gafni is silent as to moving the test element so it is presumed to be at a constant position. More important, there are only two alternative ways to position the device relative to the measurement point, one is constant and the other is variable. Absent any showing of unexpected benefit, it would have been obvious in the art to either position the device at a constant or variable spacing as such is taken to be well within the purview of choice in the art. Moreover, varying the distance would have been an obvious test method to try in order to test for nerve sensitivities.
- Regarding claim 5, Gafni uses a skin temperature sensor to send information back to the computer to influence the test protocol (column 2, lines 50-54).

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references set forth in numbered paragraph 7 as applied to claim 1 above, and further in view of WO 03/000124. None of the references in numbered paragraph 7 teaches using 3 superimposed light beam for determining the measuring point. However, WO, drawn to a measuring probe for a human body, teaches using two intersecting light beam for measuring the distance between the probe and the human body. Moreover, one in the art would have reasonably recognized and appreciated that more than two converging beams could be used effectively to calculate a measurement of a distance in space. For these reasons, it would have been obvious in the art to use two or three intersecting



light beam in the modified device of Gafni in order to accurately determine the distance between the device and human body and since one in the art would have recognized that whether two or three light beams are used, the same desired expected result of enabling one to obtain an accurate distance measurement would have been achieved.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Demand (US 4759712) as applied to claim 6 above, and further in view of Servos (US 3995620). Demand doesn't teach that the device is capable of adjusting the air stream. However, Servos teaches an airflow testing device with a flow adjust control (17), which adjusts volume of air (Figure 1). It would have been obvious to one having ordinary skill in the art to put the control on Demand's device in order to have the correct amount of air for making accurate measurements at different body areas.

10. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Demand (US 4759712) as applied to claim 10 above, and further in view of Potter (WO 03/000124). Demand doesn't teach using light sources in the form of LEDs or laser diodes with intersecting beams at a predetermined spacing from the device. However, Potter teaches a diagnostic temperature probe with pair of LEDs (22) that are positioned to create mutually converging beams (24) at a predetermined distance (page 7, lines 4-7, Figure 1). It would have been obvious in light of Potter to use LEDs on Demand's device in order to ensure a desired spacing between the device and the point being measured.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Danega whose telephone number is (571) 270-3639. The examiner can normally be reached on Monday through Thursday 7:30-5:00 eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (517) 272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RAD

/Sam Chuan C. Yao/

Supervisory Patent Examiner, Art Unit 4111

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